DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

OsseoFuse, Inc.
C/O Priscilla Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, CA 92831

Re: K133050
Trade/Device Name: One Plus Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endossesous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 20, 2014
Received: August 21, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133050

Device Name
One Plus Implant System

Indications for Use *(Describe)*

The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

(K133050)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 09/17/2014

1. Applicant / Submitter

OsseoFuse, Inc.

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2. Submission Correspondent

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3. Device

- Trade Name: One Plus Implant System
- Common Name: Dental Implant
- Classification Name: Endosseous Dental Implant System
- Product Code: DZE
- Classification regulation: 21CFR872.3640

4. Predicate Device:

- MS System by OSSTEM IMPLANT CO., LTD (K083067)
- S-MINI IMPLANT SYSTEM by NEOBIOTECH CO., LTD (K112540)
- OSSEOFUSE DENTAL IMPLANT SYSTEM by Dynamic Innovations Inc. (K110577)
- Spectra System (ScrewDirect Implant) by Implant Direct LLC (K061319)
- Replace One Piece Implant by NOBEL BIOCARE UAS INC. (K023952)
- Lifecore PrimaSolo One-Piece Implant System by Lifecore Biomedical, Inc.(K050506)

5. Description:

The One Plus Implant System is a dental implant system made of Titanium 6AL 4V ELI Gr.23 alloy intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the intended use, the technology used, the material composition employed and performance chracteristics. The surface of this system has been treated with R.B.M and the abutment part has TiN coating on it.

The One Plus Implant System is available in the following sizes.

Sizes: 3.00mm (Dia.) x 11.5/13/14.5
3.75mm (Dia.) x 11.5/13/14.5
4.50mm (Dia.) x 11.5/13/14.5
5.25mm (Dia.) x 11.5/13/14.5

6. Indication for use:

The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.

7. Basis for Substantial Equivalence

The subject device is substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented. Based on the comparison analysis, the identical intended use, comparable technological characteristics, and similar general design features, the subject device is substantially equivalent to the predicate devices. There are no significant differences between the One Plus Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the predicate devices in design, function, material and intended use.

The comparison chart can be found on the following pages.

Comparison Chart

	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4
510(K) Number	K133050	K083067	K112540	K110577	K061319
Device Name	One Plus Implant System	MS System	S-MINI IMPLANT SYSTEM	OSSEOFUSE DENTAL IMPLANT SYSTEM	Spectra System (ScrewDirect Implants)
Applicant	OsseoFuse Co., Ltd.	OSSTEM Implant Co., Ltd.	NEOBIOTECH CO., LTD.	Dynamic Innovations Inc.	Implant Direct LLC
Contract Manufacturer	KJ Meditech Co., Ltd.	-	-	KJ Meditech Co., Ltd.	-
Indications for Use	The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only. The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for	The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.	The OsseoFuse Dental Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.	The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established. The ScrewDirect 3.0mm implant is indicated for: 1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors

		immediate loading.			and maxillary lateral incisors. 2. Multiple tooth replacements or denture stabilization.
Design	One Piece Implant	One Piece Implant	One Piece Implant	Two Piece Implant	One Piece Implant
Appearance					
Material	Ti 6Al 4V ELI, Gr.23	Titanium Alloy	Titanium Gr. 4	Ti 6Al 4V ELI, Gr.23	Titanium Alloy
Surface Treatment	▪RBM Treatment on the fixture body ▪TiN coating on the abutment	RBM Treatment on the fixture body	RBM Treatment on the fixture body	▪RBM Treatment on the fixture body ▪TiN coating on the abutment	Roughened – HA blasted
Implant Sterile	Yes	Yes	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma	Gamma	Gamma
Implant Diameters	3.00mm, 3.75mm, 4.50mm, 5.25mm	2.50mm 3.00mm	2.0mm, 2.5mm, 3.0mm, 3.5mm	3.75mm, 4.1mm, 4.5mm, 5.25mm	3.0mm, 3.7mm, 4.7mm, 5.7 mm
Implant Lengths	11.5mm, 13mm, 14.5mm	10.0 mm, 13.0mm, 15.0mm	7.0 – 15.00 mm	8.5mm – 16.0 mm	10mm, 13mm, 16mm
Product Code	DZE	DZE	DZE	DZE, NHA	DZE

	Predicate Device 5	Predicate Device 6
510(K) Number	K023952	K050506
Device Name	Replace One Piece Implant	Lifecore PrimaSolo™ One-Piece Implant System
Applicant	NOBEL BIOCARE UAS INC.	LIFECORE BIOMEDICAL, INC.
Indications for Use	The Replace One Piece Implant is a threaded one-piece implant with an integrated abutment, designed for single-stage surgical procedure and cemented restorations. The Replace One Piece Implant is intended for immediate load on single tooth and multiple tooth applications in good quality bone, to restore chewing function.	Lifecore Biomedical Dental Implant System implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Specific Intended Uses: The PrimaSolo One-Piece (3.5-5.0mm) Implant is a threaded one-piece implant with integrated abutment designed for single-stage surgical procedure and cemented restorations. The PrimaSolo One-Piece Implant is intended for immediate placement and can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone. The PrimaSolo One-Piece (3.0mm) Implant is a threaded one-piece implant with an integrated abutment designed for single-stage surgical procedure and is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. Mandible central and lateral incisors must be splinted if using two or more 3.0mm implants adjacent to one other.
Design	One Piece Implant	One Piece Implant

Appearance		
Material	Titanium Gr. 4	Titanium Alloy
Surface Treatment	-	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes
Sterilization Method	-	-
Implant Diameters	3.5mm, 4.3mm, 5.0mm,	3.0mm, 3.5mm, 4.1mm, 5.0mm
Implant Lengths	10mm, 13mm, 16mm	10.0 mm, 11.5mm 13.0mm, 15.0mm

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137-1, ISO 11137-2 and ISO 11137-3.
- Accelerated shelf life testing has been performed in accordance with ASTM1980-07, ISO 11607-1, ISO 11737-1, ISO 11737-2
- Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixture.

There might be differences in sterilization parameters, shelf life and manufacturing processes between the subject device and the predicate devices, however, the test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

The subject device and the predicate devices have the same intended use and have similar technological characteristics.

Overall, the One Plus Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the One Plus Implant System is substantially equivalent to the predicate devices.